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T-D

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/935,629	09/23/97	BATES	E

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IM62/1025

EXAMINER

ALEXANDER, L

ART UNIT	PAPER NUMBER
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1743

17

DATE MAILED: 10/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/935,629

Applicant(s)

Bates et al.

Examiner

Lyle A. Alexander

Group Art Unit

1743



☒ Responsive to communication(s) filed on Aug 25, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 8, and 23-44 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 8, and 23-44 ^{34, 37-44} is/are rejected.

☒ Claim(s) 35-36 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claim Rejections - 35 USC § 112

1. Claims 25-26 and claim 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

See the appropriate paragraph of paper 14.

Claim 44 does not fulfill the preamble that requires a means and a method steps for drug analysis.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1,8, 23-34 and 42-44 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Senior(USP 5,504,013).

See the appropriate paragraph of paper 14.

With respect to new claims 42-44, Senior teaches a broad lateral face(18), a narrow lateral face(14) and a narrow end face defining a cartridge/cassette(10) that contains a test strip(16), a window(17) for viewing the results and a well/opening separate from the window(13) for containing the test strip(16). In column 2 lines 30-37 teach the cap “should

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seal the bibulous sample receiving member from the surrounding environment after sample collection”.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Senior.
See the appropriate paragraph of paper 14.

6. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Senior further in view of Owens et al. Or Ullman.

See the appropriate paragraph of paper 14.

Allowable Subject Matter

7. Claims 35-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 8/25/2000 have been fully considered but they are not persuasive.

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Applicants state “empty space” means there is nothing in the space which has special significance in view of Senior where the space is filled. The instant claims are directed to a device and the term “empty space” does not provide a further structural limitation to the device. Closed claim language (e.g. consisting essentially of) might be employed to exclude additional elements.

In response to applicant's argument that Senior and the pending invention differ in their methods of use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicants state the Office has improperly applied In re Boesch. The Office maintains Boesch has been properly applied in that modification of variables with well known and predictable results (such as fixing a cap, depositing a sample by a pipette and photocopying) are within the skill of the art.

In response to applicant's arguments against the references Senior, Owens and Ullman, individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Applicants 37 CFR 1.132 Declaration was not convincing because the arguments were not commensurate in scope with the claimed subject matter. The Declaration states Senior and the instant invention differ in structure and methods of use. However, the instant claims are indistinguishable from Senior.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is (703) 308-3893.


LYLE A. ALEXANDER
PRIMARY EXAMINER